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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343F]

**Controlled Substances:
Final Adjusted Aggregate Production Quotas for 2011**

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2011 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4564.

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, DEA published in the Federal Register on December 20, 2010, notice of the established 2011 aggregate production quotas for controlled substances in Schedules I and II (75 FR 79404). That notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2011 as provided for in 21 CFR 1303.13. The 2011 proposed adjusted aggregate production quotas were subsequently published in the Federal Register on September

14, 2011, (76 FR 56810) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before October 14, 2011.

The September 14, 2011, proposed adjusted aggregate production quotas also included proposed aggregate production quotas for five newly scheduled substances. On March 1, 2011, the DEA Administrator published a final order (76 FR 11075) which temporarily placed five synthetic cannabinoids in Schedule I: 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200); 1-Butyl-3-(1-naphthoyl)indole (JWH-073); 1-Pentyl-3-(1-naphthoyl)indole (JWH-018); 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol; and 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol. That final order stated that quotas for the five substances would be “established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations.” 76 FR 11077. Aggregate production quotas for these newly scheduled substances had not been previously established and were initially proposed in the above referenced notice published in the Federal Register on September 14, 2011 (76 FR 56810). All interested persons were invited to comment on or object to the proposed aggregate production quotas on or before October 14, 2011.

Analysis for Final Adjusted 2011 Aggregate Production Quotas

Consideration has been given to the criteria outlined in the September 14, 2011, notice of proposed adjusted aggregate production quotas in accordance with 21 CFR 1303.13. In addition, six companies, four DEA registered manufacturers and two non-registrants, submitted timely comments regarding a total of 22 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 4-anilino-N-phenethyl-4-piperidine (ANPP), alfentanil, amphetamine (for sale), diphenoxylate, fentanyl, gamma hydroxybutyric acid,

hydrocodone, meperidine, methadone, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), pentobarbital, secobarbital, sufentanil, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. DEA has taken into consideration the above comments along with the relevant 2010 year-end inventories, initial 2011 manufacturing quotas, 2011 export requirements, actual and projected 2011 sales, research and product development requirements, and additional applications received.

Based on all of the above, the Administrator has determined that the proposed adjusted 2011 aggregate production quotas for alfentanil, diphenoxylate, gamma hydroxybutyric acid, meperidine, and pentobarbital required additional consideration and hereby further adjusts the 2011 aggregate production quotas for those substances.

Regarding 4-anilino-N-phenethyl-4-piperidine (ANPP), amphetamine (for sale), fentanyl, hydrocodone, methadone, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), secobarbital, sufentanil, and thebaine, the Administrator hereby determines that the proposed adjusted 2011 aggregate production quotas for these substances as published on September 14, 2011, at 76 FR 56810 are sufficient to meet the current 2011 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

Pursuant to the above, the Administrator hereby establishes the 2011 final aggregate production quotas for Schedule I and II controlled substances, including the five newly

scheduled substances previously referenced, expressed in grams of anhydrous acid or base, as follows:

Basic Class – Schedule I	Final Adjusted 2011 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g

Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	5,772,000 g
Heroin	20 g
Hydromorphenol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Final Adjusted 2011 Quotas
1-Phenylcyclohexylamine	2 g
1-Piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g

Alfentanil	12,800 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	8,500,000 g
Amphetamine (for sale)	25,300,000 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	255,000 g
Diphenoxylate	730,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	59,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	2 g
Levo-alphaacetylmethadol (LAAM)	3 g
Levomethorphan	2 g
Levorphanol	3,600 g
Lisdexamfetamine	10,400,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
Methylphenidate	56,000,000 g
Morphine (for conversion)	70,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	10,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	63,000 g
Opium (tincture)	1,000,000 g
Oripavine	8,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,070,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g

Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanyl	2,500 g
Secobarbital	336,002 g
Sufentanyl	5,000 g
Tapentadol	403,000 g
Thebaine	116,000,000 g

Aggregate production quotas for all other Schedule I and II controlled substances included in 21

CFR 1308.11 and 1308.12 remain at zero.

Dated:
December 1, 2011

Michele M. Leonhart
Administrator

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